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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10,018,700	06/20/2002	Martin James Ford	PG3692USW	7782

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/018,700

Applicant(s)

FORD ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 30 is/are allowed.
- 6) ☐ Claim(s) 15, 17, 18, 26, 28, 29 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 20 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### Detailed Action

The Abstract is objected to. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specifically, use of legal phraseology "said" in line 3 of the Abstract is objected to.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 15, 17-18, 26 and 28 are rejected under 35 USC 102(c) as being anticipated by Chung et al.

Applicants claim a method for the propagation of lytic organisms (i.e. viruses such as adenoviruses) comprising providing a hollow fiber bioreactor containing multiple hollow fibers and having a stable cell line growing in the extracapillary space (ECS) of the bioreactor, introducing the lytic organisms into the ECS and allowing the lytic organism to infect the cell, multiply within the cells and harvesting the lytic organism from the bioreactor. Applicants define a "stable cell line" as any cell line that **is capable of growing** in the extracapillary space to populations of  $10^6$  cells/ml.

Chung et al. (U.S. Patent 6,342,384, issued 01/29/02, filed 11/17/98, see whole document, particularly the Abstract, column 2, lines 44-65; column 4, lines 11-67 and Table 2) recites a method for the propagation of lytic viruses (such as recombinant or non-recombinant adenoviruses) comprising providing a hollow fiber bioreactor containing multiple hollow fibers (Chung et al. recite (specification, column 4, lines 11-16) that any capillary systems including, specifically, "Cellmax" SPS and MPS systems from Cellco Inc., which can have multiple hollow fibers, can be used) and having a stable cell line growing in the ECS of the bioreactor, introducing the lytic organism into the ECS and allowing the lytic organism to infect the cells, multiply within the cells and harvesting the lytic organism from the bioreactor. With regard to the 293 cells used by Chung et al. being a "stable cell line", it is noted that Chung et al. inoculates the bioreactor with  **$5 \times 10^7$  293 cells** and allows the cells to grow until the lactate levels

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reach 500 mg/day. The prior art indicates that 293 cells are routinely grown to populations of  $10^6$  cells/ml in media with or without serum (see for example, Carrion et al., U.S. Patent 6,383,795, filed 4/22/99, see especially example 2 in column 9) for infection by adenoviruses and therefore it must be assumed, absent evidence to the contrary, that the 293 cells are capable of reaching population levels of  $10^6$  cells/ml in the media in bioreactors. Chung et al. therefore teaches the claimed invention. It is also noted that secondary (extrinsic) evidence or references can be used in a 35 USC 102 rejection to show that a feature of the claimed invention is inherent in a prior art anticipatory teaching which is otherwise silent about said inherent feature (See MPEP 2131.01).

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites a method for "...studying the effects of molecules on a lytic organism...", but the method steps do not recite what effects will be studied and how they will be studied. For example, the last step of the method merely recites adding a test compound to the bioreactor and determining (by undisclosed means) the effects of the test compound on the lytic organism.

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Also, the preamble of the claim recites a method for studying the effects of "molecules" on a lytic organism but the method steps only recite adding a "test compound" to the bioreactor, is the molecule of the preamble the same molecule as the test compound?

Claim 31 refers to the "method" of claim 30; however, claim 30 recites a hollow fiber bioreactor, not a method.

Claims 16, 19-25, 27 and 29-31 are free of the art because the art does not teach or suggest the specific cell densities in the bioreactor prior to the time of infection with the lytic organism, does not teach expression of recombinant proteins of interest by the infected cells in the bioreactor, does not teach the recited cell survival times post infection, does not teach re-populating the bioreactor with the cells remaining in the bioreactor after harvesting the lytic organism, does not teach the lytic organism being a baculovirus and does not teach a method for studying the effects of test compounds on lytic organisms using the recited bioreactor system. The closest prior art is represented by Chung et al. (cited above).

Claim 30 is allowed.

Claims 16, 19-25 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

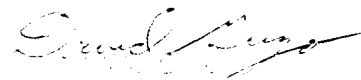
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
September 2, 2003

  
PRIMARY EXAMINER